IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP., Defendants.	)	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Complaint against Defendants Par Pharmaceutical, Inc. ("Par"), and IntelGenX Technologies Corp. ("IGX") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant Par's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of United States Patent Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

2. Plaintiffs also seek a declaratory judgment that: (1) some of Defendant Par's notices of Paragraph IV certification are premature, null and void, and ineffective to trigger the

ANDA patent litigation process in Case No. 1:13-cv-01461-RGA; and (2) there is no subject matter jurisdiction over Plaintiffs' claims and Defendants' counterclaims in Case No. 1:13-cv-01461-RGA because Defendant Par's premature notices are null and void.

THE PARTIES

3. Plaintiff RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

4. Plaintiff RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

5. Plaintiff MonoSol is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

6. On information and belief, Defendant Par is a Delaware corporation having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

7. On information and belief, Defendant IGX is a Delaware corporation having a principal place of business at 6425 Abrams, Ville St-Laurent (Quebec), Canada.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. On information and belief, Par is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

10. Par has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example by bringing the patent infringement suit *Par Pharmaceutical Inc. v. Breckenridge Pharmaceutical Inc.*, C.A. No. 13-1114-SLR.

11. This Court has personal jurisdiction over Par because of, *inter alia*, Par's incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of this judicial district, and its marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

12. On information and belief, IGX is a drug delivery company focused on the development of oral controlled-release products as well as rapidly disintegrating delivery systems.

13. IGX, directly or through its affiliates, has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example by voluntarily substituting in as defendant in the patent infringement suit *Biovail Laboratories International SRL v. IntelGenx Corp.*, C.A. No. 09-605-LPS.

14. This Court has personal jurisdiction over IGX because of, *inter alia*, IGX's incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, and its previous submission to the jurisdiction of this judicial district.

15. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

16. Plaintiff RBP UK is the lawful owner of the '832 patent, and Plaintiff RBP is an exclusive licensee of the '832 patent. The '832 patent, entitled "Sublingual and Buccal Film Compositions," duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the '832 patent is attached hereto as Exhibit A.

17. Plaintiff MonoSol is the lawful owner of the '150 patent, and Plaintiff RBP is an exclusive licensee of the '150 patent. The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," duly and legally issued on September 13, 2011, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '150 patent is attached hereto as Exhibit B.

18. Plaintiff MonoSol is the lawful owner of the '514 patent, and Plaintiff RBP is an exclusive licensee of the '514 patent. The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," duly and legally issued on December 10, 2013, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '514 patent is attached hereto as Exhibit C.

SUBOXONE® SUBLINGUAL FILM

19. Plaintiff RBP is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

20. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. Plaintiff RBP has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

21. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

THE DRUG APPROVAL PROCESS

22. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355.

The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that innovator drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

23. Under 21 U.S.C. § 355(b)(1), the innovator drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

24. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDAs can rely on FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-approved drug.

25. When a generic manufacturer submits an ANDA, the FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. *See* 21 C.F.R. § 314.101(b)(1). "Receipt of an [ANDA] means that FDA has made a threshold

determination that the abbreviated application is sufficiently complete to permit a substantive review." *Id.*

26. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV certifications").

27. Paragraph IV certifications can allow generic manufacturers to obtain FDA approval long before expiration of the patents listed in the Orange Book.

28. If the ANDA includes a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice ("notice of Paragraph IV certification") to the patent owner of the factual and legal basis for the applicant's opinion that patents listed in the Orange Book are invalid or will not be infringed, "not later than 20 days after the date of the postmark on the notice with which the [FDA] informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B).

29. The patent owner can file an infringement action within 45 days of receiving the notice of Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of the FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

30. The date of receipt of the notice of Paragraph IV certification by the patent owner affects important rights and remedies of the patent owner, including the deadline for filing an infringement action and the start and end dates of the 30-month injunction. By providing a premature notice of Paragraph IV certification to the NDA holder or patent owner, the ANDA applicant attempts to trigger the 30-month injunction earlier and to reach the market sooner than it would otherwise be permitted. In addition, there is a significant risk for the patent owner to miss the 45-day deadline for filing an infringement action, and consequently the opportunity for a 30-month injunction, if the patent owner mistakenly relies on a premature and ineffective notice of Paragraph IV certification.

31. The ANDA applicant may not send the notice of Paragraph IV certification to the patent owner before the FDA "informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B)(ii)(I); *SB Pharmco Puerto Rico, Inc. v. Mut. Pharm. Co., Inc.*, 552 F. Supp. 2d 500, 508 (E.D. Pa. 2008); *Otsuka Pharm. Co. v. Par Pharm., Inc.*, Docket No. 13-1979 (D. Del. March 10, 2014) (Andrews, J.).

32. Federal regulations also govern the timing of the notice of Paragraph IV certification by directing the generic manufacturer to send such notice "when it receives from FDA an acknowledgment letter stating that its [ANDA] is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

DEFENDANTS' ANDA AND PREMATURE NOTICES OF PARAGRAPH IV CERTIFICATION

33. Plaintiffs received a letter from Defendant Par dated July 8, 2013 (the "July 2013 Notice Letter"), stating that ANDA No. 20-5854 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '832 and '150 patents are

invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

34. The July 2013 Notice Letter further states that Defendant Par submitted ANDA No. 20-5854 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Defendants' generic product") before expiration of the patents-in-suit.

35. On information and belief, ANDA No. 20-5854 refers to and relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

36. On information and belief, ANDA No. 20-5854 was prepared and submitted with the active cooperation, participation, and assistance of, and at least in part for the benefit of, Defendant IGX. On information and belief, if ANDA No. 20-5854 is approved, IGX will actively participate in manufacturing, marketing, and/or selling Defendants' generic product.

37. On information and belief, IGX designed Defendants' generic product that is the subject of Defendant Par's ANDA No. 20-5854.

38. On information and belief, Defendants' generic product that is the subject of Defendant Par's ANDA No. 20-5854 includes IGX's VersaFilm™ drug delivery technology.

39. IGX filed statements with the SEC in 2013 asserting that IGX's "U.S. based co-development and commercialization partner" submitted an ANDA to the FDA for approval of a generic formulation of Plaintiff RBP's Suboxone® sublingual film, indicated for maintenance treatment of opioid dependence.

40. Plaintiffs filed suit against Defendants in this judicial district on August 20, 2013 (Case No. 1:13-cv-01461-RGA), within 45 days of receiving the July 2013 Notice Letter.

41. Plaintiffs received another letter from Defendant Par dated February 3, 2014 ("the '514 Notice Letter"), stating that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '514 patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

42. Plaintiffs amended their complaint in Case No. 1:13-cv-01461-RGA on February 18, 2014, within 45 days of receiving the '514 Notice Letter, to further assert the infringement of the '514 Patent under 35 U.S.C. § 271(e)(2).

43. Plaintiffs received yet another letter from Defendant Par dated March 25, 2014 (the "March 2014 Notice Letter"), repeating that ANDA No. 20-5854 contains a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '832, '150, and '514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

44. The March 2014 Notice Letter further states that Defendant Par submitted ANDA No. 20-5854 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of Defendants' generic product, i.e. buprenorphine hydrochloride and naloxone hydrochloride sublingual film, before expiration of the patents-in-suit.

45. Unlike the earlier notices of Paragraph IV certifications (which include the July 2013 Notice Letter and the '514 Notice Letter), the March 2014 Notice Letter represents that the FDA "has received [ANDA No. 20-5854] for substantive review."

46. On information and belief, Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, were sent before receiving the FDA's acknowledgment letter stating that ANDA No. 20-5854 is sufficiently complete to permit a substantive review.

47. Recent authority from this judicial district demonstrates that Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature and ineffective to trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of Defendants' ANDA No. 20-5854. *See Otsuka Pharm. Co. v. Par Pharm., Inc.*, Docket No. 13-1979 (D. Del. March 10, 2014) (Andrews, J.).

48. Plaintiffs commenced this action within 45 days of receiving the March 2014 Notice Letter, to preserve their right to a 30-month stay under 21 U.S.C. 355(j)(5)(B)(iii).

COUNT I
(Declaratory Judgment)

49. Plaintiffs reallege paragraphs 1-48 above as if fully set forth herein.

50. On information and belief, Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, were sent before receiving the FDA's letter stating that ANDA No. 20-5854 is sufficiently complete to permit a substantive review.

51. Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature, null and void, and ineffective to trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of ANDA No. 20-5854.

52. An actual, substantial, and justiciable controversy exists between Defendants and Plaintiffs regarding whether Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature, null, void, and ineffective to trigger the ANDA litigation process in Case No. 1:13-cv-01461-RGA.

53. The controversy concerning the validity and effectiveness of Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, will

cause Plaintiffs to suffer substantial prejudice and irreparable harm, unless the controversy and its surrounding uncertainty are resolved by the Court. Defendant Par attempts to trigger the 30-month injunction earlier and to reach the market sooner than it would otherwise be permitted. In addition, there is a significant risk for Plaintiffs to miss the 45-day deadline for filing an infringement action, and consequently the opportunity for a 30-month injunction, if they mistakenly rely on Defendant Par's premature and ineffective notices of Paragraph IV certification.

54. Plaintiffs are entitled to a declaration that: (1) Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature, null and void, and ineffective to trigger the ANDA patent litigation process in Case No. 1:13-cv-01461-RGA; (2) Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, did not trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of Defendants' ANDA No. 20-5854; and (3) there is no subject matter jurisdiction over Plaintiffs' claims and Defendants' counterclaims in Case No. 1:13-cv-01461-RGA because Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are null and void.

COUNT II
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

55. Plaintiffs reallege paragraphs 1-54 above as if fully set forth herein.

56. On information and belief, Defendants' generic product is covered by one or more claims of the '832 patent.

57. By filing ANDA No. 20-5854 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of

Defendants' generic product prior to the expiration of the '832 patent, Par has committed an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

58. On information and belief, IGX was actively involved in the preparation and are actively involved in the prosecution before the FDA of ANDA No. 20-5854.

59. IGX's active assistance and involvement with the submission of ANDA No. 20-5854 is an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

60. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5854 to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

COUNT III
(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

61. Plaintiffs reallege paragraphs 1-60 above as if fully set forth herein.

62. On information and belief, Defendants' generic product is covered by one or more claims of the '150 patent.

63. By filing ANDA No. 20-5854 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '150 patent, Par has committed an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

64. On information and belief, IGX was actively involved in the preparation and are actively involved in the prosecution before the FDA of ANDA No. 20-5854.

65. IGX's active assistance and involvement with the submission of ANDA No. 20-5854 is an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

66. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, inter *alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5854 to be a date which is not any earlier than the expiration date of the '150 patent, including any extensions of that date.

COUNT IV
(Infringement of the '514 Patent Under 35 U.S.C. § 271(e)(2))

67. Plaintiffs reallege paragraphs 1-66 above as if fully set forth herein.

68. On information and belief, Defendants' generic product is covered by one or more claims of the '514 patent.

69. ANDA No. 20-5854 under 21 U.S.C. § 355(j) seeks to obtain approval to engage in the commercial manufacture, use, sale and/or importation of Defendants' generic product prior to the expiration of the '514 patent. Therefore, Par's maintenance of this filing constitutes an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

70. On information and belief, IGX was actively involved in the preparation and are actively involved in the prosecution before the FDA of ANDA No. 20-5854.

71. IGX's active assistance and involvement with the submission of ANDA No. 20-5854 is an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

72. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5854 to be a date which is not any earlier than the expiration date of the '514 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Preliminarily and permanently enjoin Par to withdraw its earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter;

B. Enter a declaratory judgment that: (1) Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are premature, null and void, and ineffective to trigger the ANDA patent litigation process in Case No. 1:13-cv-01461-RGA; (2) Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, did not trigger the 45-day period for filing an infringement action and the 30-month injunction on FDA approval of Defendants' ANDA No. 20-5854; and (3) there is no subject matter jurisdiction over Plaintiffs' claims and Defendants' counterclaims in Case No. 1:13-cv-01461-RGA because Defendant Par's earlier notices of Paragraph IV certifications, which predate the March 2014 Notice Letter, are null and void;

C. Enter a judgment that Defendants have infringed each of the patents-in-suit under 35 U.S.C. § 271(e)(2) by submitting and maintaining ANDA No. 20-5854;

D. Enter preliminary and permanent injunctions, restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patents-in-suit;

E. Enter an order that the effective date of any approval of ANDA No. 20-5854 be a date that is not earlier than the expiration of the last to expire of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with those patents;

F. Enter a judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

G. Enter a judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendants commercially manufacture, use, offer to sell, or sell in the United States, or import into the United States, Defendants' generic product before the expiration of each patent-in-suit that Defendants are found to infringe, including any extensions; and

H. Order any and all other relief as the Court deems just and proper.

Dated: April 4, 2014

Respectfully submitted,

WOMBLE CARLYLE SANDRIDGE & RICE, LLP

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